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IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORP. and
HOLOGIC L.P.,

Plaintiffs,

v.

SENORX, INC.,

Defendant.

) Case No. 08-CV-0133 RMW
)
) **DEFENDANT SENORX, INC.'S REPLY**
) **MEMORANDUM IN SUPPORT OF ITS**
) **MOTION FOR PARTIAL SUMMARY**
) **JUDGMENT OF NON-INFRINGEMENT**
) **('813 PATENT, CLAIMS 11 & 12; '204**
) **PATENT, CLAIMS 4 & 17)**
)
) Date: June 25, 2008
) Time: 2:00 p.m.
) Courtroom: 6, 4th Floor
) Judge: Hon. Ronald M. Whyte

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ARGUMENT IN REPLY

There are only two issues presented in SenoRx's motion for summary judgment of non-infringement: 1) can a device using only one radiation source infringe a claim requiring a "plurality" of radiation sources; and 2) can a device where the spacing between the radionuclide and the balloon changes infringe a claim requiring that the spacing be constant. As a matter of law, the answer to both questions is no. Despite Plaintiffs' disjointed brief in opposition – which careens back and forth through irrelevant questions of direct and indirect infringement, the alleged development of Plaintiffs' device, and other tangents that were not raised by SenoRx in its motion for summary judgment – there are no disputed facts relevant to the two issues here.

First, there is no factual dispute that only one radiation source is ever placed in the Contura during use, and never two or more. *See* Pls. Opp. at 3. This requires a finding of non-infringement of claim 12 of the '813 patent and claim 17 of the '204 patent as a matter of law.¹ Plaintiffs' position is that because this single source is moved to different locations in the device during a patient's treatment, it is thereby transformed into a "plurality" of radiation sources. That is nonsense – placing a single radiation source in multiple locations in a device no more transforms a single source into multiple sources than parking the same car in different parking spaces means that someone has two cars.

Second, there is no factual dispute that Contura users "typically employ more than one 'dwell point' during a procedure." Pls. Opp. at 3. As to those uses, Plaintiffs argue that a radioactive source moving within a balloon can satisfy claim limitations requiring constant spacing between the source and the balloon if there exists a single snapshot in time in which the source is located in the center of the balloon. That is wrong. The predetermined spacing claim limitations require not only that the closest distance from any point on the source to the balloon be the same (*i.e.*, the inner and outer volumes must have the same shape and be concentric), but also that it is unchanging (*i.e.*, fixed) rather than variable. Because it is undisputed that the

¹ Plaintiffs have dropped their assertions that claim 6 of the '142 patent is infringed, and accordingly that claim is not further discussed herein.

1 radionuclide moves among the dwell positions in the Contura during its use, thereby changing
 2 the spacing between the radiation source and the balloon, summary judgment of non-
 3 infringement on the predetermined spacing limitations for those uses should be granted. Nor are
 4 the predetermined spacing limitations met for the handful of remaining uses (literally a dozen or
 5 so performed in limited pre-launch, post-approval testing of the Contura), in which the radiation
 6 source was placed in the center of the balloon, as there cannot be constant spacing between a
 7 cylindrical source and a spherical balloon as a matter of fact or law.

8 Notably, Plaintiffs' theories as to the plurality and predetermined spacing limitations are
 9 completely inconsistent. Because claim 12 of the '813 patent is a dependent claim, it requires
 10 both a predetermined constant spacing (claim 1) and a plurality of sources (claim 12). Plaintiffs
 11 "snapshot" theory of infringement for purposes of satisfying the constant spacing limitation
 12 would mean that there is not a plurality of sources; the single source used in the Contura cannot
 13 be in two locations simultaneously. Conversely, Plaintiffs' plurality argument requires the
 14 radionuclide to be in motion, which by definition means there is no constant spacing.

15 Plaintiffs' arguments here fatally undermine function of patent claims of "'appris[ing] the
 16 public of what is still open to them.'" *Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d
 17 1573, 1581 (Fed. Cir. 1996) (*quoting McClain v. Ortmyer*, 141 U.S. 419, 424 (1891)). This
 18 Court should, as a matter of law, reject Plaintiffs' attempts to escape the consequence of the
 19 application of the undisputed facts to this claim language, and grant summary judgment of non-
 20 infringement of the subject claims to SenoRx.

21 **I. A DEVICE DOES NOT INFRINGE IF IT IS MERELY "CAPABLE" OF BEING**
 22 **USED IN AN INFRINGING WAY.**

23 Rather than respond to SenoRx's arguments and evidence, Plaintiffs wish to focus on a
 24 different inquiry. According to Plaintiffs, the issue is whether the Contura is capable of being
 25 configured in an infringing way. Thus, Plaintiffs place great weight on their erroneous
 26 contention that "[i]nfringement of an apparatus claim is determined based on the capabilities of
 27 an accused device's structure not its actual method(s) of use." *See* Pls. Opp. at 6. This
 28 proposition is a plain misstatement of the law. The controlling authority on this point, *Cross*

1 *Medical Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1311-12 (Fed. Cir.
 2 2005), directly contradicts Plaintiffs' position, as discussed in SenoRx's opening brief. *See*
 3 SenoRx Br. at 7-8. *Cross Medical* specifically rejected the argument that infringement occurred
 4 if an accused device was "capable" of being configured to infringe. 424 F.3d at 1311. Rather,
 5 the court held that the device must actually contain all of the structural limitations of the claim:
 6 "to infringe an apparatus claim, the device must meet all of the [claim's] structural limitations."
 7 *Id.* (emphasis added). Plaintiffs do not even mention, much less attempt to distinguish, *Cross*
 8 *Medical*. Instead, Plaintiffs cite cases either distinguished by *Cross Medical* (*Intel*) or relied on
 9 by *Cross Medical* in support of the Federal Circuit's conclusion that a device does not infringe a
 10 claim if it is merely capable of infringing (*NTP*, *Hewlett-Packard*, and *In re Michlin*). *See Cross*
 11 *Medical*, 424 F.3d at 1311-12.²

14 ² *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1317-18 (Fed. Cir. 2005) stands for
 15 the unremarkable proposition that, for purposes of determining whether infringement has
 16 occurred "within the United States," the concept of "use" in method claims is different than in
 17 apparatus claims. In *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464, 1468 (Fed.
 18 Cir. 1990), the court, in discussing an apparatus claim in a prior art reference, noted that
 19 "[a]pparatus claims cover what a device is, not what a device does." SenoRx agrees – but here,
 20 to know what the device is, one has to know how it is actually configured when it is used. Third,
 21 in *In re Michlin*, 256 F.2d 317, 320 (CCPA 1958), the CCPA noted that "[i]t is well settled that
 22 patentability of apparatus claims must depend upon structural limitations and not upon
 23 statements of function." Again, this is entirely consistent with the requirement in *Cross Medical*
 24 that an accused device, in order to infringe, must meet all of the claim's structural limitations.
 25 *See Cross Medical*, 424 F.3d at 1311-12.

26 Plaintiffs also rely heavily on *Intel Corp. v. U.S. Int'l Trade Commission*, 946 F.2d 821,
 27 832 (Fed. Cir. 1991) to support their erroneous contention that "[i]nfringement of an apparatus
 28 claim is determined based on the capabilities of an accused device's structure." Pls. Opp. 6, 9-
 10. The Federal Circuit in *Cross Medical* and other cases has distinguished *Intel* based on the
 claim language, explaining that because the claim at issue in *Intel* called for a "programmable
 selection means," this claim language required only that an accused device included the means
 that made it capable of operating in the enumerated mode. 424 F.3d at 1311; *see also Fantasy*
Sports Props, Inc. v. SportsLine.com, Inc., 287 F.3d 1108, 1117-18 (Fed. Cir. 2002)
 (emphasizing the programmable claim language in *Intel* and holding that *Intel* "does not stand
 for the proposition . . . that infringement may be made based upon a finding that an accused
 product is merely capable of being modified in a manner that infringes the claims of a patent);
Zygo Corp. v. Wyko Corp., 79 F.3d 1563, 1570 (Fed. Cir. 1996) (noting that the patentee
 overread *Intel* since the claim "[b]y its literal terms" only required "capability"); *High Tech Med.*
Instrumentation, Inc. v. New Image Inds., Inc., 49 F.3d 1551, 1555-56 (Fed. Cir. 1995)
 (distinguishing *Intel* based on the "programmable" claim limitation).

1 Similarly, Plaintiffs accuse SenoRx of improperly treating their apparatus claims as
 2 “method” claims. But it is undisputed that until the device is configured with a radioactive
 3 source in the body of a patient, all of the elements required for direct infringement do not exist.
 4 The fact that the claims provide that the apparatus only exists when a radiation source is inside a
 5 balloon during treatment of a patient does not convert the claims to method claims. And SenoRx
 6 does not argue to the contrary. SenoRx’s argument is that an infringing apparatus never exists.
 7 In an attempt to create a factual issue, Plaintiffs spend much of their brief citing to SenoRx
 8 marketing materials and arguing that SenoRx infringes either directly and indirectly. While this
 9 is factually wrong, it is completely irrelevant to this motion and misses the point. What SenoRx
 10 does or does not do is immaterial where, as here, at no point is the Contura (as used by anyone)
 11 configured to fall under the claims. This motion is based solely on the fact that there never is a
 12 plurality of sources and that there never is a predetermined spacing in the Contura as required by
 13 the claims.

14 **II. PLURALITY.**

15 **A. There Is No Dispute of Material Fact That the Contura Does Not Literally** 16 **Infringe the “Plurality” Limitations.**

17 The “plurality of radioactive solid particles” limitation of the ’813 patent and the
 18 “plurality of solid radiation sources” limitation of the ’204 patent require that the claimed
 19 devices contain two or more radiation sources. Plaintiffs do not dispute that the Contura uses
 20 only a single source. It therefore does not infringe.

21 Plaintiffs’ response to the undisputed facts is to ignore the claim limitations and try to
 22 rewrite them. Plaintiffs assert that the Contura literally infringes the claims because:

23 a solid radionuclide on a source wire can be (and is) inserted
 24 sequentially into multiple predetermined locations within one or
 25 more of the Contura’s treatment lumens to provide a “desired
 composite radiation profile” within the targeted tissue.

26 Pls. Opp. 15. But the claims do not require “a solid radionuclide on a source wire.” They
 27 require a “plurality” of “solid radiation sources” (claim 17) or “solid particles” (claim 12). And,
 28 contrary to Plaintiffs’ assertions, the claims do not merely require that radiation is emitted from

multiple locations, but rather that there are multiple radiation sources: claim 12 specifically recites an apparatus with “a plurality of radioactive solid particles placed at predetermined locations.” Plaintiffs would read claim 12 as requiring “a radioactive solid particle placed at predetermined locations,” reading out the term “plurality” entirely and erroneously rendering it wholly superfluous. *See Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) (“Allowing a patentee to argue that physical structures and characteristics specifically described in a claim are merely superfluous would render the scope of the patent ambiguous, leaving examiners and the public to guess about which claim language the drafter deems necessary to his claimed invention and which language is merely superfluous, nonlimiting elaboration.”).

Plaintiffs criticize SenoRx for importing aspects of the preferred embodiments into the claims. Pls. Opp. at 16. SenoRx has done nothing of the sort. The claims themselves require a “plurality” of “sources” or “particles.” Moreover, the specification itself makes clear that Plaintiffs construction is incorrect, expressly distinguishing between a “single” radiation source and a “plurality” of sources in a manner fundamentally inconsistent with Plaintiffs’ position (and consistent with SenoRx’s): the radiation source “instead of comprising a single solid sphere, may comprise a plurality of radiation emitting particles strategically placed” Ex. 1 (’813 patent), col. 2:66-3:1; Ex. 2 (’204 patent), col. 5:2-4. Thus, both the claims and the specification preclude Plaintiffs interpretation of “plurality.”

Plaintiffs also argue that “the focus of the ‘plurality’ claim terms is on emitting radiotherapeutic rays from multiple locations,” Pls. Opp. at 3, and the “objective of these claims” is to provide for emitting radiation from “multiple locations.” Pls. Opp. at 16. Put another way, pay no attention to what the inventors actually claim, just focus on the gist of what they must have meant. That is not how the patent system works. “‘The invention’ is defined by the claims,” *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1565 (Fed. Cir. 1991), and both the claims here require a plurality of sources, not simply a plurality of locations. Plaintiffs are asking this Court to rewrite the claims in a manner that contradicts the express language of the claims to cover a competitor’s device that falls outside the claim’s scope. That Plaintiffs need to do so speaks volumes about the fact that the Contura does not infringe the claims as actually written.

1 Because the insertion of a single solid radionuclide into multiple locations does not
 2 literally infringe claims requiring a “plurality” of radiation sources or particles, the Contura does
 3 not infringe.

4 **B. The Contura Does Not Infringe the “Plurality” Limitations Under the**
 5 **Doctrine of Equivalents As a Matter of Law.**

6 Understandably concerned that the Court will not construe a requirement for two or more
 7 radiation sources to cover a single radiation source, Plaintiffs belatedly seek to assert the doctrine
 8 of equivalents.³ But they cannot do so as a matter of law. First, employing the doctrine of
 9 equivalents here would vitiate the “plurality of . . . sources” limitation of the claims and violate
 10 the “all elements rule.” Put simply, Plaintiffs may not ignore completely the requirement they
 11 inserted into their claims that there be a plurality of radiation sources in the claimed devices
 12 under the guise of asserting infringement by equivalents. *See, e.g., Warner-Jenkinson Co. v.*
 13 *Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997) (“Each element contained in a patent claim is
 14 deemed material to defining the scope of the patented invention It is important to ensure
 15 that the application of the doctrine [of equivalents], even as to an individual element, is not
 16 allowed such broad play as to effectively eliminate that element in its entirety.”).

17 For example, in *Moore U.S.A. v. Std. Register Co.*, 229 F.3d 1091, 1106 (Fed. Cir. 2000),
 18 one of the patents-in-suit related to a “mailer type business form,” and the claim limitation
 19 required that “strips of adhesive . . . extend the majority of the lengths” of the mailer. *Id.* at
 20 1094. In the accused product, the strips extended 47.8% of the total margin length. *Id.* at 1097.
 21 The Federal Circuit held, as a matter of law, that the “majority” claim limitation could not reach
 22 the accused product under the doctrine of equivalents:

23 ³ As explained in SenoRx’s accompanying Motion to Strike, Plaintiffs’ eleventh-hour change
 24 in course comes far too late and would unfairly prejudice SenoRx if allowed. Plaintiffs served
 25 infringement contentions on May 6, 2008, and for the “plurality” claim elements, asserted only
 26 literal infringement, even though the doctrine of equivalents was asserted for many other claim
 27 limitations. Ex. 4 (Pls’ Infr. Cont. Appx. A) at 4, 9, 15; (Pls’ Infr. Cont. Appx. B) at 4-5, 7, 16-
 28 17. If the Court permits Plaintiffs to belatedly assert infringement under the doctrine of
 equivalents, SenoRx will suffer unfair prejudice given that the six inventors of the patents have
 been deposed, the deadline to serve new discovery has passed, expert reports have been served,
 and the parties are one month from trial.

[T]o allow what is undisputedly a minority (*i.e.*, 47.8%) to be equivalent to a majority would vitiate the [claim] requirement. . . . [I]t would defy logic to conclude that a minority -- the very antithesis of a majority -- could be insubstantially different from a claim limitation requiring a majority, and no reasonable juror could find otherwise.

Id. at 1106. *Accord Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc.*, 291 F.3d 1317, 1321-22 (Fed. Cir. 2002) (affirming summary judgment of no infringement under doctrine of equivalents where the claim required a port to be located “between” two plugs and the accused product had its port located “above” the plug, holding that the patentee “cannot escape application of the all-limitations rule by recharacterizing its claim so as to ignore a material limitation”); *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1424 (Fed. Cir. 1997) (holding that the doctrine of equivalents does not grant a license to remove structural limitations contained in the patent claims); *Conopco, Inc. v. May Dept. Stores Co.*, 46 F.3d 1556, 1562 (Fed. Cir. 1994) (“The doctrine of equivalents cannot be used to erase meaningful structural and functional limitations of the claim on which the public is entitled to rely in avoiding infringement.”); *Dolly, Inc. v. Spalding & Evenflo Cos.*, 16 F.3d 394, 398 (Fed. Cir. 1994) (“The doctrine of equivalents is not a license to ignore claim limitations.”).

In the present case, Plaintiffs’ claims require as a structural element of the claimed device that there be multiple radiation sources. Just as a “minority” cannot be the equivalent of a “majority,” it cannot be, as a matter of law, that a device that uses only one radiation source is the equivalent of having multiple radiation sources. To allow such equivalence completely eliminates the structural requirement that there be more than one radiation source, and is the “precise type of overextension of the doctrine of equivalents that the claim vitiation doctrine is intended to prevent.” *Freedman Seating Co. v. Am. Seating Co.*, 420 F.3d 1350, 1362 (Fed. Cir. 2005).

The principle of specific exclusion (a corollary of the all elements rule), requires the same result. The concept underlying the specific exclusion principle is the common sense notion that when a patentee affirmatively chooses a claim term whose very meaning restricts the scope

1 of the claim, a patentee cannot then recapture under the doctrine of equivalents the claim scope
2 specifically excluded. The Federal Circuit has explained:

3 [I]f a patent states that the claimed device must be “nonmetallic,”
4 the patentee cannot assert the patent against a metallic device on the
5 ground that a metallic device is equivalent to a non-metallic device.
6 The unavailability of the doctrine of equivalents could be explained
7 either as the product of an impermissible vitiation of the “non-
8 metallic” claim limitation, or as the product of a clear and binding
9 statement to the public that metallic structures are excluded from the
10 protection of the patent.

11 *SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337, 1346-47
12 (Fed. Cir. 2001). Thus, in a case with a claim limitation strikingly similar to “plurality,” the
13 Federal Circuit applied this doctrine to hold that a claim requiring “at least three values”
14 specifically excludes a system with “only two” values, and that accordingly there was no
15 equivalence as a matter of law. *Athletic Alternatives v. Prince Mfg.*, 73 F.3d 1573, 1382-83
16 (Fed. Cir. 1996). Likewise, the Federal Circuit held that a claim requiring that objects be
17 “mounted” specifically excludes coverage under the doctrine of equivalents of objects that are
18 “unmounted.” *Asyst Techs., Inc. v. Emtrak, Inc.*, 402 F.3d 1188, 1195 (Fed. Cir. 2005); *see also*,
19 *e.g.*, *Freedman Seating Co.*, 420 F.3d at 1362 (holding that “slidably mounted” could not be
20 equivalent to “rotatably mounted,” and noting that members of the public were justified in
21 relying on the specific claim language: “to now say that the claims include [an element of the
22 accused product] under the doctrine of equivalents would unjustly undermine the reasonable
23 expectations of the public”); *Bicon, Inc.*, 441 F.3d at 955 (holding as a matter of law that
24 “concave” could not be equivalent to “convex”); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1160
25 (Fed. Cir. 1998) (to hold that a device with a hemispherical shape infringes a patent requiring
26 that the device have a “generally conical outer surface” would “write the ‘generally conical outer
27 surface’ limitation out of the claims”); *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 149
28 F.3d 1309, 1317 (Fed. Cir. 1998) (subject matter is “specifically excluded” from coverage under
the doctrine of equivalents if its inclusion is “inconsistent with the language of the claim”).

Here, Plaintiffs’ choice to claim a device having a “plurality” of solid sources specifically
excludes devices containing only a “single” solid radiation source, and that exclusion cannot be

1 recaptured under the doctrine of equivalence without erasing the requirement altogether. “The
 2 patents contain a distinct limitation, which was part of the bargain when the patent issued,” and
 3 this Court “cannot overlook a distinct claim limitation or expand the doctrine of equivalents
 4 beyond its purpose to allow recapture of subject matter excluded by a deliberate and foreseeable
 5 claim drafting decision.” *Planet Bingo, LLC v. Gametech Int’l, Inc.*, 472 F.3d 1338, 1344 (Fed.
 6 Cir. 2006). Plaintiffs must be held to their “deliberate and foreseeable claim drafting decision.”
 7 *Id.* As such, there is “no . . . material issue for the jury to resolve, and a judgment of non-
 8 infringement under the doctrine of equivalents . . . is appropriate.” *See Cook Biotech Inc. v.*
 9 *ACell, Inc.*, 460 F.3d 1365, 1379 (Fed. Cir. 2006). Thus, to the extent Plaintiffs are allowed to
 10 belatedly assert this doctrine, summary judgment of non-infringement under the doctrine of
 11 equivalents should be entered as to claim 12 of the ’813 patent and claim 17 of the ’204 patent.

12 **III. THE CONTURA DOES NOT MEET THE PREDETERMINED SPACING** 13 **LIMITATIONS.**

14 Plaintiffs’ Opposition abandons their contention that there is predetermined spacing
 15 between the treatment lumens (either individually or together) and the balloon of the Contura.
 16 Plaintiffs defend only their third theory of how the predetermined spacing limitations are
 17 satisfied, which requires that the radionuclide source in the Contura be deemed the inner spatial
 18 volume. Plaintiffs’ position is that if the radionuclide in the Contura stops at the center of the
 19 Contura’s central lumen, at that moment, there is infringement. Plaintiffs do not contend that
 20 there is infringement under treatment plans where the radionuclide does not stop in the center of
 21 the central lumen.

22 Plaintiffs devote a great deal of effort to describing ways the Contura could be used, in
 23 hopes of establishing a fact issue as to infringement. But Plaintiffs have not presented evidence
 24 that raises a dispute of fact about how the Contura is actually used, which is the pertinent
 25 inquiry, and none of the treatment plans utilized with the Contura meet the predetermined
 26 spacing limitations. Accordingly, summary judgment on predetermined spacing is warranted.

27 Fundamentally, there are three relevant categories of treatment plans: (1) plans that do
 28 not utilize the central lumen, central dwell position, (2) plans utilizing the central lumen, central

1 dwell position as one of multiple dwell positions, and (3) plans utilizing only the central lumen,
2 central dwell.

3 SenoRx's construction of the '813 and '204 patents is identical, and if adopted, summary
4 judgment is appropriate as to each of the three categories. Plaintiffs' construction differs
5 between the two patents. If Plaintiffs' construction is adopted with respect to the '813 patent,
6 summary judgment nonetheless still is appropriate. If Plaintiffs' construction is adopted with
7 regard to the '204 patent, SenoRx acknowledges that there is a factual dispute as to each of the
8 three treatment plans and that summary judgment therefore is not appropriate. These are
9 addressed in turn below.

10 **1. Treatment Plans That Do Not Use the Central Lumen, Central Dwell**
11 **Position.**

12 If SenoRx's construction is adopted, Plaintiffs do not dispute that the first category of
13 treatment plans do not meet the predetermined spacing limitations of either patent because the
14 radionuclide never comes to rest at the central lumen, central dwell position, which is required
15 by Plaintiffs' theory of infringement. Even under Plaintiffs' construction, the '813 patent is not
16 infringed because the only basis for infringement is the central lumen, center dwell position,
17 which is not used in this category. [REDACTED]

18 [REDACTED]
19 [REDACTED]
20 [REDACTED] Accordingly, this category need not be discussed
21 further and the Court should enter partial summary judgment of non-infringement of the '813
22 patent for this category of use, and if SenoRx's construction of the '204 patent is adopted, as to
23 the '204 patent as well.

24 **2. Treatment Plans Utilizing Multiple Dwell Positions Including the**
25 **Central Lumen, Central Dwell Position.**

26 If SenoRx's construction is adopted and the spacing must be "fixed," summary judgment
27 of non-infringement of both patents is appropriate because the spacing changes as the
28 radionuclide moves from dwell position to dwell position and, accordingly, is not fixed. [REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]⁴

Plaintiffs respond that as long as the source dwells in the center of the central lumen, at that point in time the spacing is “fixed,” even if the radiation source also dwells in other positions during treatment. Plaintiffs reason that at the moment the radionuclide stops at this center position, there is constant spacing in all directions from the radionuclide to the balloon. Pls. Op. 8. Plaintiffs stop their analysis here, deeming it irrelevant whether before or after stopping in the center of the device, the radionuclide is in other locations where the distances to the balloon are not the same. Plaintiffs are wrong. The spacing between a radiation source and a balloon is not “constant” if that spacing changes as the radionuclide moves to different points within the balloon. To say, as Plaintiffs’ theory requires, that the spacing is constant for the period of time until the spacing changes ignores the concept that the spacing must be constant. Thus, the issue with regard to this element is not simply whether there is a moment where the spacing between the radionuclide and the balloon is the same in all directions, but also whether this spacing stays the same during use of the device. If it does not, then the spacing is not constant. Put another way, to meet this limitation the spacing between the radiation source and the balloon must be fixed and unchanging. [REDACTED]

[REDACTED]

If, on the other hand, Plaintiffs’ construction is adopted, the analysis is the same as that stated below in category 3 for the ’813 patent, and summary judgment with respect to category 2 is appropriate for that reason as well.

⁴ The reasons stated below with respect to category 3 provide an independent reason why summary judgment is appropriate under SenoRx’s construction for category 2.

1 **3. Treatment Plans Utilizing Only the Central Lumen, Central Dwell**
 2 **Position.**

3 The final category of Contura treatment plans are those in which only the central dwell of
 4 the central lumen is used. Plaintiffs argue that a treatment plan utilizing only this central
 5 position meets the predetermined spacing limitations. Pls. Opp. 9-11. While Plaintiffs have no
 6 evidence that such treatment plans have actually been used since the January 2008 commercial
 7 launch, that is beside the point.⁵ The Contura still does not infringe the predetermined spacing
 8 limitations as a matter of law.

9 Under either side's construction, the '813 patent is not infringed because it is undisputed
 10 that the radionuclide used with the Contura is cylindrical. See Pls. Opp. 11-12. [REDACTED]

11 [REDACTED]
 12 [REDACTED] Even assuming a treatment plan making exclusive use of the central lumen, central dwell
 13 position, there still would not be infringement because there cannot be constant spacing between
 14 a cylindrical radionuclide and a spherical balloon. See Orton Decl. ¶ 36. That is because the
 15 cylindrical radionuclide is not the same shape as the spherical outer balloon, (SenoRx's
 16 construction), nor is the radionuclide the same distance in all directions from the outer balloon
 17 because the radionuclide cylinder is three times longer than it is wide (Plaintiffs' construction of
 18 claims 11, 12 of the '813 patent). SenoRx Br. 14-15.

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 20 _____
 21 ⁵ SenoRx does not dispute that there was limited use of the Contura in this manner in the past
 22 (although it is not being used that way by anyone any more). Although it is not necessary to our
 23 motion that the Court so find, the undisputed evidence is that this is not how the Contura is used.
 24 Gearhart Decl. (5/20/08) ¶ 8. [REDACTED]
 25 [REDACTED]
 26 [REDACTED]
 27 [REDACTED]
 28 [REDACTED]

Citing language in the specification absent from the claims, Plaintiffs argue that the spacing required by the claim is merely “substantially,” “generally,” and “somewhat,” constant. But this misses the point. The issue is not whether a radiation source and balloon must both be perfectly spherical, such that there is exactly the same distance between them in all directions. The reason the Contura does not infringe this claim element is more fundamental. It is clear from the specification and prosecution history that the spacing limitation requires that the radionuclide and the balloon be the same shape. In each embodiment of both patents, the inner spatial volume and the outer balloon are the same shape, and in the prosecution history of both patents, Plaintiffs distinguish prior art on the basis that the shapes of the two volumes are different. *See* SenoRx Br. 14-15; Ex. 8 (Sept. 1, 1998 Am., ’813 Prosecution History), at 5,7; Ex. 9 (Dec. 20, 2000 Am., ’204 Prosecution History), at 12. Because a cylinder is not the same shape as a sphere, this requirement is not met even as to central lumen, central dwell position.

* * * * *

In sum, as a matter of law, the “predetermined constant spacing” and “predetermined spacing” limitations are not met by the Contura. The device has multiple lumens and multiple dwell positions through which the radionuclide is moved throughout the treatment. As a result, the spacing is not constant. And because the shape of the radionuclide is different than the shape of the balloon, the spacing is not constant even if it were not moved from the central position.

CONCLUSION

For the foregoing reasons, the Court should grant SenoRx’s Motion for Partial Summary Judgment of Non-Infringement.

Dated: June 11, 2008

Respectfully submitted,

By: /s/ F.T.Alexandra Mahaney

F.T. Alexandra Mahaney, State Bar No. 125984
WILSON SONSINI GOODRICH & ROSATI
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Bruce R. Genderson (admitted *pro hac vice*)
Aaron P. Maurer (admitted *pro hac vice*)
Rachel Shanahan Rodman (admitted *pro hac vice*)
Adam D. Harber (admitted *pro hac vice*)
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Attorneys for Defendant
SENORX, INC.

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CERTIFICATE OF SERVICE
U.S. District Court, Northern District of California,
Hologic, Inc. et al. v. SenoRx, Inc.
Case No. C-08-0133 RMW (RS)

I, Janice Wright, declare:

I am and was at the time of the service mentioned in this declaration, employed in the County of San Diego, California. I am over the age of 18 years and not a party to the within action. My business address is 12235 El Camino Real, Ste. 200, San Diego, CA, 92130.

On June 11, 2008, I served a copy(ies) of the following document(s):

**DEFENDANT SENORX, INC.'S REPLY MEMORANDUM IN SUPPORT OF ITS
MOTION FOR PARTIAL SUMMARY JUDGMENT OF NON-INFRINGEMENT
(‘813 PATENT, CLAIMS 11 AND 12; ‘204 PATENT, CLAIMS 4 AND 17)
[REDACTED VERSION]**

on the parties to this action by the following means:

Henry C. Su (suh@howrey.com)
Katharine L. Altemus (altemusk@howrey.com)
HOWREY LLP
1950 University Avenue, 4th Floor
East Palo Alto, CA 94303
Telephone: (650) 798-3500
Facsimile: (650) 798-3600

Attorneys for Plaintiffs
HOLOGIC, INC. CYTYC
CORPORATION and
HOLOGIC LP

Matthew Wolf (wolfm@howrey.com)
Marc Cohn (cohnm@howrey.com)
HOWREY LLP
1229 Pennsylvania Avenue, NW
Washington, DC 20004
Telephone: (202) 783-0800
Facsimile: (202) 383-6610

Attorneys for Plaintiffs
HOLOGIC, INC. CYTYC
CORPORATION and
HOLOGIC LP

☒ (BY MAIL) I placed the sealed envelope(s) for collection and mailing by following the ordinary business practices of Wilson Sonsini Goodrich & Rosati, 12235 El Camino Real, Ste. 200, San Diego, CA. I am readily familiar with WSGR's practice for collecting and processing of correspondence for mailing with the United States Postal Service, said practice being that, in the ordinary course of business, correspondence with postage fully prepaid is deposited with the United States Postal Service the same day as it is placed for collection.

☒ (BY ELECTRONIC MAIL) I caused such document(s) to be sent via electronic mail (email) to the above listed names and email addresses.

☐ (BY PERSONAL SERVICE) I caused to be delivered by hand to the addressee(s) noted above. I delivered to an authorized courier or driver to be delivered on the same date. A proof of service signed by the authorized courier will be filed with the court upon request.


☐ (BY OVERNIGHT DELIVERY) I placed the sealed envelope(s) or package(s), to the addressee(s) noted above, designated by the express service carrier for collection and overnight delivery by following the ordinary business practices of Wilson Sonsini

1 Goodrich & Rosati, 12235 El Camino Real, Ste. 200, San Diego, CA. I am readily
2 familiar with WSGR's practice for collecting and processing of correspondence for
3 overnight delivery, said practice being that, in the ordinary course of business,
4 correspondence for overnight delivery is deposited with delivery fees paid or provided for
5 at the carrier's express service offices for next-day delivery the same day as the
6 correspondence is placed for collection.

7 ☐ (BY FACSIMILE) I caused to be transmitted by facsimile machine (number of sending
8 facsimile machine is (858) 350-2399 at the time stated on the attached transmission
9 report(s) by sending the documents(s) to (see above). The facsimile transmission(s)
10 was/were reported as complete and without error.

11 ☒ (BY CM/ECF) I caused such document(s) to be sent via electronic mail through the Case
12 Management/Electronic Case File system with the U.S. District Court for the Northern
13 District of California.

14 I declare under penalty of perjury under the laws of the United States that the above is true
15 and correct, and that this declaration was executed on June 11, 2008.

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Janice Wright

F.T. Alexandra Mahaney, State Bar No. 125984
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Bruce R. Genderson (*admitted pro hac vice*)
Aaron P. Maurer (*admitted pro hac vice*)
Rachel Shanahan Rodman (*admitted pro hac vice*)
Adam D. Harber (*admitted pro hac vice*)
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Attorneys for Defendant
SENORX, INC.

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORP. and
HOLOGIC L.P.,

Plaintiffs,

v.

SENORX, INC.,

Defendant.

) Case No. 08-CV-0133 RMW

) **DECLARATION OF ADAM D.**
) **HARBER IN SUPPORT OF**
) **DEFENDANT SENORX, INC.'S**
) **REPLY IN SUPPORT OF ITS**
) **MOTION FOR PARTIAL SUMMARY**
) **JUDGMENT OF NON-**
) **INFRINGEMENT**

) Date: June 25, 2008

) Time: 2:00 p.m.

) Courtroom: 6, 4th Floor

) Judge: Hon. Ronald M. Whyte

1 I, Adam D. Harber, declare that I am an associate at the law firm of Williams & Connolly
 2 LLP, admitted pro hac vice to practice before this Court in the above-captioned matter. I serve
 3 as outside counsel for Defendant SenoRx, Inc. The following declaration is based on my
 4 personal knowledge, and if called upon to testify, I could and would competently testify as to the
 5 matters set forth herein.

6 1. Attached hereto as Exhibit 6¹ is a true and correct copy of excerpts of the
 7 transcript of the Deposition of Lynn J. Verhey (Nov. 14, 2006), from the case captioned Xoft,
 8 Inc. v. Cytoc Corp., et al., Case Number C-05-05312 RMW, in the United States District Court
 9 for the Northern District of California.

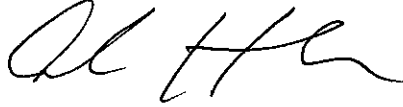
10 2. Attached hereto as Exhibit 7 is a true and correct copy of excerpts of the transcript
 11 of the Deposition of James F. Dempsey (May 24, 2008).

12 3. Attached hereto as Exhibit 8 is a true and correct copy of the September 1, 1998
 13 Amendment from the Patent Prosecution History for U.S. Patent No. 5,913,813.

14 4. Attached hereto as Exhibit 9 is a true and correct copy of the December 20, 2000
 15 Amendment from the Patent Prosecution History for U.S. Patent No. 6,413,204.

16
 17 I declare under penalty of perjury that the foregoing is true and correct.

18
 19 Dated: June 11, 2008

20 By: 
 Adam D. Harber

21
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 26 ¹ The numbers assigned to exhibits attached to this Declaration run consecutively from the
 27 exhibit numbers of those attached to the Declaration of Adam D. Harber in Support of Defendant
 28 SenoRx, Inc.'s Motion for Partial Summary Judgment of Non-Infringement.

CERTIFICATE OF SERVICE
U.S. District Court, Northern District of California,
Hologic, Inc. et al. v. SenoRx, Inc.
Case No. C-08-0133 RMW (RS)

I, Janice Wright, declare:

I am and was at the time of the service mentioned in this declaration, employed in the County of San Diego, California. I am over the age of 18 years and not a party to the within action. My business address is 12235 El Camino Real, Ste. 200, San Diego, CA, 92130.

On June 11, 2008, I served a copy(ies) of the following document(s):

**DECLARATION OF ADAM D. HARBER IN SUPPORT OF DEFENDANT
SENORX, INC.' REPLY MEMORANDUM IN SUPPORT OF ITS MOTION FOR
PARTIAL SUMMARY JUDGMENT OF NON-INFRINGEMENT**

on the parties to this action by the following means:

| | |
|--|--------------------------|
| Henry C. Su (suh@howrey.com) | Attorneys for Plaintiffs |
| Katharine L. Altemus (altemusk@howrey.com) | HOLOGIC, INC. CYTYC |
| HOWREY LLP | CORPORATION and |
| 1950 University Avenue, 4th Floor | HOLOGIC LP |
| East Palo Alto, CA 94303 | |
| Telephone: (650) 798-3500 | |
| Facsimile: (650) 798-3600 | |

| | |
|---------------------------------|--------------------------|
| Matthew Wolf (wolfm@howrey.com) | Attorneys for Plaintiffs |
| Marc Cohn (cohnm@howrey.com) | HOLOGIC, INC. CYTYC |
| HOWREY LLP | CORPORATION and |
| 1229 Pennsylvania Avenue, NW | HOLOGIC LP |
| Washington, DC 20004 | |
| Telephone: (202) 783-0800 | |
| Facsimile: (202) 383-6610 | |

☒ (BY MAIL) I placed the sealed envelope(s) for collection and mailing by following the ordinary business practices of Wilson Sonsini Goodrich & Rosati, 12235 El Camino Real, Ste. 200, San Diego, CA. I am readily familiar with WSGR's practice for collecting and processing of correspondence for mailing with the United States Postal Service, said practice being that, in the ordinary course of business, correspondence with postage fully prepaid is deposited with the United States Postal Service the same day as it is placed for collection.

☒ (BY ELECTRONIC MAIL) I caused such document(s) to be sent via electronic mail (email) to the above listed names and email addresses.

☐ (BY PERSONAL SERVICE) I caused to be delivered by hand to the addressee(s) noted above. I delivered to an authorized courier or driver to be delivered on the same date. A proof of service signed by the authorized courier will be filed with the court upon request.

☐ (BY OVERNIGHT DELIVERY) I placed the sealed envelope(s) or package(s), to the addressee(s) noted above, designated by the express service carrier for collection and overnight delivery by following the ordinary business practices of Wilson Sonsini Goodrich & Rosati, 12235 El Camino Real, Ste. 200, San Diego, CA. I am readily

1 familiar with WSGR's practice for collecting and processing of correspondence for
2 overnight delivery, said practice being that, in the ordinary course of business,
3 correspondence for overnight delivery is deposited with delivery fees paid or provided for
at the carrier's express service offices for next-day delivery the same day as the
correspondence is placed for collection.

4 ☐ (BY FACSIMILE) I caused to be transmitted by facsimile machine (number of sending
5 facsimile machine is (858) 350-2399 at the time stated on the attached transmission
report(s) by sending the documents(s) to (see above). The facsimile transmission(s)
was/were reported as complete and without error.

6 ☒ (BY CM/ECF) I caused such document(s) to be sent via electronic mail through the Case
7 Management/Electronic Case File system with the U.S. District Court for the Northern
District of California.

8 I declare under penalty of perjury under the laws of the United States that the above is true
9 and correct, and that this declaration was executed on June 11, 2008.

10 
11 Janice Wright

Exhibit 8

#7/A



PATENT APPLICATION

OUR FILE NO. 970344.ORI

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re App : Jeffery A. Williams, et al.
S.N. : 08/900,021 : September 1, 1998
Filed : July 24, 1997 : Art Unit 3736
For : DOUBLE WALL BALLOON CATHETER
FOR TREATMENT OF
PROLIFERATIVE TISSUE : Examiner J. Lacyk

ASSISTANT COMMISSIONER FOR PATENTS

WASHINGTON, D.C. 20231

Dear Sir:

Responsive to the first Official Action of May 12, 1998,
please amend the above-captioned application as follows:

IN THE CLAIMS:

Please cancel Claim 12.

Please amend the following claims:

1 (Amended). Apparatus for delivering radioactive
emissions to a body location with a [controlled] uniform
radiation profile, comprising:

(a) a catheter body member having a proximal end and
distal end;

(b) an inner spatial volume disposed [at] proximate
the distal end of the catheter body member;

(c) an outer, closed, [distensible] inflatable
chamber defined by a radiation transparent wall [disposed at]

affixed to the body member proximate the distal end [of the body member] thereof in surrounding relation to the inner spatial volume with a predetermined constant spacing between said inner spatial volume and the radiation transparent wall;

(d) a material containing a radionuclide(s) disposed in one of the inner spatial volume and outer chamber; and

(e) means disposed in the other of the inner spatial volume and outer chamber for [controlling] rendering uniform the radial absorbed dose profile of the emissions from the one of the inner spatial volume and outer chamber containing the radionuclides.

2 (Amended). The apparatus as in Claim 1 wherein said inner spatial volume is an inner closed, [distensible] chamber defined by a further radiation transparent wall.

3 (Amended). The apparatus of Claim 1 wherein the means for [controlling] rendering uniform the absorbed dose profile is a radiation attenuating material.

4 (Amended). The apparatus of Claim [2] 3 wherein the radiation [absorbing fluid] attenuating material is selected from a group consisting of barium sulphate, water, and X-ray contrast media.

8 (Amended). The apparatus as in Claim [1] 2 wherein the inner chamber contains the radioactive material.

10 (Amended). The apparatus as in [any one of Claims 7 or] Claim 8 wherein the radioactive material is a fluid.

11 (Amended). The apparatus as in [any one of Claims 7 or]

11 Claim 8 wherein the radioactive material is a solid.

12 12 (Amended). The apparatus as in Claim 1 wherein the material containing a radionuclide comprises a plurality of

15 radioactive solid particles [are] placed at predetermined locations within the inner spatial volume to provide a desired composite radiation profile.

1 Please add the following claim:

13 14. The apparatus as in Claim 2 wherein the inner and outer chambers are spherical in shape and are concentric.

R E M A R K S

This Amendment is submitted in response to the first Official Action of May 12, 1998. Reconsideration and allowance of Claims 1-11 and 13, as presently amended, are respectfully requested.

The present invention is directed to an apparatus for treating proliferative tissue disorders by delivering radioactive emissions to target tissue within the body with a uniform radial absorbed dose profile whereby diseased tissue may be irradiated with sufficient intensity to kill disease cells, but without producing necrosis of neighboring healthy tissue. With the apparatus of the present invention, it is possible to deliver a desired radiation dose at a predetermined radial distance from a source of radioactivity by providing a catheter body member having an inner spatial volume disposed proximate the distal end of the catheter body and with an outer, closed, inflatable,

chamber defined by a radiation transparent wall affixed to the body member proximate the distal end thereof in a surrounding relation to the inner spatial volume with a predetermined constant spacing between the inner spatial volume and the radiation transparent wall. A material containing a radionuclide is introduced through the catheter body in either the inner spatial volume or the outer chamber and the other of the inner spatial volume or outer chamber not containing the radionuclide is made to contain a radiation attenuating material for rendering uniform the radial absorbed dose profile of the emissions from the one of the inner spatial volume and outer chamber that contains the radionuclide.

In the Official Action, objection was raised to Claims 4 and 13 under 35 U.S.C. §112, second paragraph, as being indefinite. Claim 13 has been amended to clarify that the material containing a radionuclide as recited in claim 1 comprises "a plurality of radioactive solid particles". Claim 4 has been amended by changing "radiation absorbing fluid" to -- radiation attenuating material --, the latter phrase finding an antecedent in Claim 3 from which it now depends.

Concerning the rejection on the merits, Claims 1-5, 8 and 10 were rejected under 35 U.S.C. §102(b) as being anticipated by Ishiwara et al. This rejection is respectfully traverse. Before it is appropriate to find a claim anticipated under 35 U.S.C. §102(b), it is necessary to find within the four corners of the prior art reference relied upon a full teaching of each and every

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element of the claims sought to be anticipated. As Claim 1 has now been amended, it calls for an outer, closed, inflatable chamber located proximate the distal end of a catheter body member in surrounding relation to an inner spatial volume such that there is a predetermined constant spacing between the inner spatial volume and the radiation transparent wall. There is then provided a means disposed in the chamber, not having the radiation source, a substance for rendering uniform the radial absorbed dose profile of the emissions from the chamber that contains the radiation source. In the Ishiwara et al. '360 patent relied upon for anticipation, the outer chamber defined by the radiation transparent wall 12 cannot provide a uniform radiation profile. The outer balloon 12 in the Ishiwara et al. patent functions only to stabilize the device within and hold a thermal mass (liquid) against surrounding tissue so that it can be warmed or cooled by thermal conduction. There is no teaching or suggestion in the patent of how to provide a uniform radial absorbed dose profile of emissions emanating from the liquid radiation source 38. Moreover, given the banana shape of the Ishiwara device, the profile will be much different proximate the distal and proximal ends of the balloon 12 than in its central tissue contacting region. Thus, it cannot be said that applicants' invention, as claimed, is taught by or inherent in the Ishiwara '360 device.

Given the above mentioned differences, neither Claim 1 nor any of the remaining dependent claims is anticipated by the

Ishiwara et al. teachings. It is further submitted that the invention of Claim 1 is not rendered obvious from the teachings of the Ishiwara et al. patent.

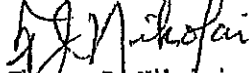
While admittedly the present invention and the device described in the Ishiwara et al. patent have some points of similarity, i.e., both are catheters having an outer closed inflatable chamber and an inner spatial volume surrounded by the outer chamber and both are designed to provide radiation therapy to a tumor site, that is where the similarity ends. Applicants' invention is specifically designed to provide a uniform radial absorbed dose profile of the emissions from the particular chamber containing the radionuclide material so that occurrences of "hot spots" and/or "cold spots" are substantially eliminated. Hot spots can result in necrosis of healthy tissue, a condition to be avoided, while cold spots may mean that cancerous cells are not irradiated and killed. In one embodiment, uniformity of the radial absorbed profile is achieved by providing a spherical outer chamber which when inflated to contact the margins resulting following surgical removal of the tumor, a desired constant spacing will be maintained between the radiation source and the adjacent tissue structures. In a second embodiment, attention is paid to the spacing between the inner and outer radiation transparent walls so that it is constant over the entire surfaces of the two chambers. Given these important distinctions which are neither taught nor suggested by the Ishiwara reference, applicants' independent Claim 1, as amended,

is not made obvious from the prior art. In fact, it is proper to say that the Ishiwara et al. reference teaches away from applicants' invention given the elongate, cylindrical shape of the radiation source employed and the oblong-shaped outer balloon surrounding it.

In that Claim 1, as amended, has been shown to be patentable over the prior art, and because Claims 2-11 and 13 depend directly or indirectly from Claim 1, all of the claims remaining in the application are believed to be in condition for allowance and a Notice to that effect is respectfully solicited.

Respectfully submitted,

HAUGEN AND NIKOLAI, P.A.



Thomas J. Nikolai
Attorney for Applicants
Registration No. 19283
900 Second Avenue South
Suite 820
Minneapolis, MN 55402
Phone: 612-339-7461

CERTIFICATE OF MAILING

I hereby certify that the foregoing Amendment in response to the Official Action of May 12, 1998 in application Serial No. 08/900,021 of inventors, Jeffery A. Williams et al., filed July 24, 1997, for "DOUBLE WALL BALLOON CATHETER FOR TREATMENT OF PROLIFERATIVE TISSUE" is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on September 1, 1998.

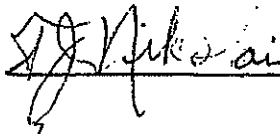
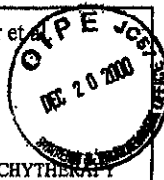
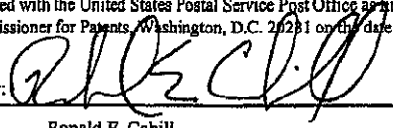


Exhibit 9

#7/A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | | |
|------------------|--|---|----------------------|
| Applicant(s): | Rance A. Winkler et al. |  | Group Art Unit: 3736 |
| Application No: | 09/293,524 | | Examiner: J. Lacyk |
| Filing Date: | April 15, 1999 | | |
| Entitled: | INTERSTITIAL BRACHYTHERAPY APPARATUS AND METHOD FOR TREATMENT OF PROLIFERATIVE TISSUE DISEASES | | |
| Atty. Docket No: | 101360-15 (ONE-008) | | |

| | |
|---|--|
| <u>Certificate of Mailing (37 C.F.R. 1.8(a))</u> | |
| I hereby certify that this correspondence is being deposited with the United States Postal Service Post Office as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on the date set forth below. | |
| December 20, 2000 | By:  |
| Date of Signature and Mail Deposit | Ronald E. Cahill Reg. No: 38,403 |

AMENDMENT AND RESPONSE

Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir:

In response to the Office Action dated June 20, 2000, please amend the above-referenced patent application as follows:

12/27/2000 MAILED 00000057 09293524

| | | |
|-----------|----------------------|-----------|
| 02 FC:202 | <u>In the claims</u> | 120.00 OP |
| 03 FC:203 | | 18.00 OP |

Please amend the claims as follows:

A

Application No: 09/293,524
Group Art Unit: 3736
Examiner: J. Lacyk
Atty Docket No: 101360-15 (ONE-008)

CLAIMS

1. (Amended) An interstitial brachytherapy apparatus for delivering radioactive emissions to an internal body location comprising:

- (a) a catheter body member having a proximal end and distal end;
- (b) an inner spatial volume disposed proximate to the distal end of the catheter body member;
- (c) an outer spatial volume defined by an expandable surface element disposed proximate to the distal end of the body member in a surrounding relation to the inner spatial volume; and
- (d) a radiation source disposed in the inner spatial volume and generating a three-dimensional isodose profile that is substantially similar in shape to the expandable surface element.

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2. (Amended) The apparatus of claim 1, wherein the inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose for delivering therapeutic effects to a target tissue [that may include cancer cells], the target tissue being defined between the outer spatial volume expandable surface and a minimum distance outward from the outer spatial volume expandable surface, the apparatus providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue proximate to the expandable surface.

A2
4. (Amended) The apparatus of claim 3, wherein the expandable surface element is adapted to contact [contacts] tissue surrounding a resected cavity and adapted to conform [conforms] the tissue to the desired shape of the expandable surface element.

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Please cancel claims 5 and 6.

~~17~~ ^{A3} (Amended) The apparatus of claim ~~13~~, wherein [the] a burst strength of the distensible chamber defining the outer spatial volume is greater than [the] a burst strength of the chamber defining the inner spatial volume.

^{A4} ~~19~~ ²¹ (Amended) A method for treating a proliferating tissue disease using interstitial brachytherapy at an internal body location comprising:

- (a) surgically creating access to the proliferating tissue in a patient;
- (b) surgically resecting at least a portion of the proliferating tissue to create a resection cavity within body tissue;
- (c) providing an interstitial brachytherapy apparatus for delivering radioactive emissions comprising:
 - (i) a catheter body member having a proximal end and distal end;
 - (ii) an inner spatial volume disposed proximate to the distal end of the catheter body member;
 - (iii) an outer spatial volume defined by an expandable surface element disposed proximate to the distal end of the body member in a surrounding relation to the inner spatial volume; and
 - (iv) a radiation source disposed in the inner spatial volume and generating a three-dimensional isodose profile that is substantially similar in shape to the expandable surface element;
- (d) intraoperatively placing the interstitial brachytherapy apparatus into the resection cavity until a prescribed absorbed dose has been delivered to tissue surrounding the apparatus; and
- (e) removing the interstitial brachytherapy apparatus.

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²⁰
22. (Amended) The method of claim ¹⁹21, further including placing [wherein] the radioactive source [is placed] into the interstitial brachytherapy apparatus after the step of placing [placement of] the apparatus into the tumor resection cavity.

²¹
23. (Amended) The method of claim ¹⁹21, further including removing [wherein] the radioactive source [is removed] from the interstitial brachytherapy apparatus before the step of removing [removal of] the apparatus.

²²
24. (Amended) The method of claim ¹⁹21, wherein the proliferating tissue is [resected from] a patient's brain.

AH ²³
25. (Amended) The method of claim ¹⁹21, wherein the proliferating tissue is [resected from] a patient's breast.

²⁴
26. (Amended) The method of claim ¹⁹21, further including configuring [wherein] the inner and outer spatial volumes [are configured] to provide a minimum prescribed absorbed dose for delivering therapeutic effects to a target tissue [that may include cancer cells], the target tissue being defined between the outer spatial volume expandable surface and a minimum distance outward from the outer spatial volume expandable surface, the apparatus providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue proximate to the expandable surface.

²⁵
27. (Amended) The method of claim ²⁴26, further including providing [wherein] a predetermined spacing [is provided] between said inner spatial volume and the expandable surface element.

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26
28. (Amended) The method of claim 25, wherein the expandable surface element is adapted to contact [contacts] tissue surrounding a resected cavity and adapted to conform [conforms] the tissue to the desired shape of the expandable surface element.

Please cancel claims 29 and 30.

Please add the following new claims:

24
31. The method of claim 26, wherein the step of configuring the inner and outer spatial volumes includes expanding the inner and outer spatial volumes.

32
36. A method for treating a proliferating tissue disease using interstitial brachytherapy at an internal body location comprising:

- A5
- (a) surgically creating access to the proliferating tissue in a patient;
 - (b) surgically resecting at least a portion of the proliferating tissue to create a resection cavity within body tissue;
 - (c) providing an interstitial brachytherapy apparatus for delivering radioactive emissions comprising:
 - (i) a catheter body member having a proximal end and distal end;
 - (ii) an inner spatial volume disposed proximate to the distal end of the catheter body member;
 - (iii) an outer spatial volume defined by an expandable surface element disposed proximate to the distal end of the body member in a surrounding relation to the inner spatial volume; and
 - (iv) a radiation source disposed in the inner spatial volume;

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(d) intraoperatively placing the interstitial brachytherapy apparatus into the resection cavity;

(e) configuring the inner and outer spatial volumes to provide a minimum prescribed absorbed dose for delivering therapeutic effects to a target tissue, the target tissue being defined between the outer spatial volume expandable surface and a minimum distance outward from the outer spatial volume expandable surface, the apparatus providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue proximate to the expandable surface; and

(f) removing the interstitial brachytherapy apparatus.

³³
37. The method of claim ³²36, wherein the step of configuring the inner and outer spatial volumes includes expanding the inner and outer spatial volumes.

³⁴
AS 38. A method for treating a proliferating tissue disease using interstitial brachytherapy at an internal body location comprising:

(a) surgically creating access to the proliferating tissue in a patient;
(b) surgically resecting at least a portion of the proliferating tissue to create a resection cavity within body tissue;

(c) providing an interstitial brachytherapy apparatus for delivering radioactive emissions comprising:

(i) a catheter body member having a proximal end and distal end;
(ii) an inner spatial volume disposed proximate to the distal end of the catheter body member;
(iii) an outer spatial volume defined by an expandable surface element disposed proximate to the distal end of the body member in a surrounding relation to the inner spatial volume; and

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- (iv) a radiation source disposed in the inner spatial volume;
- (d) intraoperatively placing the interstitial brachytherapy apparatus into the resection cavity;
- (e) adapting the expandable surface element to contact tissue surrounding the resection cavity to conform the tissue to the desired shape of the expandable surface element;
- (f) delivering a prescribed absorbed dose to tissue surrounding the apparatus; and
- (g) removing the interstitial brachytherapy apparatus.

³⁵
39. The method of claim ³⁴36, wherein the step of adapting the expandable surface element includes expanding the outer surface volume.

³⁶
AS 40. An interstitial brachytherapy apparatus for delivering radioactive emissions to an internal body location comprising:

- (a) a catheter body member having a proximal end and distal end;
- (b) an inner spatial volume disposed proximate to the distal end of the catheter body member;
- (c) an outer spatial volume defined by an expandable surface element disposed proximate to the distal end of the body member in a surrounding relation to the inner spatial volume; and

(d) a radiation source disposed in the inner spatial volume;

wherein the inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose for delivering therapeutic effects to a target tissue, the target tissue being defined between the outer spatial volume expandable surface and a minimum distance outward from the outer spatial volume expandable surface, the apparatus providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue proximate to the expandable surface.

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REMARKS

The above-identified patent application has been amended and reconsideration is respectfully requested. In response to the Examiner's rejections, Applicant hereby amends claims 1, 2, 4, 14, and 21-28. Claims 5, 6, 29, and 30 are canceled. Claims 35-40 are added. Claims 1 and 21, as amended, now recite that the interstitial brachytherapy apparatus comprises a radiation source disposed in the inner spatial volume that generates a three-dimensional isodose profile that is substantially similar in shape to the expandable surface element. Accordingly, claims 5, 6, 29, and 30 are canceled. New independent claim 36 incorporates all of the limitations of claims 21 and 26, while new independent claim 38 incorporates all of the limitations of claims 21 and 28. Also, new independent claim 40 incorporates all of the limitations of claims 1 and 2. New dependent claims 35 and 37 recite that the step of configuring the inner and outer spatial volumes includes expanding the inner and outer volumes, while new dependent claim 39 recites that the step of adapting the expandable surface element includes expanding the outer surface volume. Support for these limitations can be found on page 7, line 27 to page 8, line 15. Accordingly, no new matter is added by these amendments.

Response to the Indefiniteness Rejections

Claims 2, 4, 5, 14, and 22-29 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for unclear language and for lacking antecedent basis for certain limitations.

The Examiner rejects claims 2 and 26 for use of the phrase "may include" in line 3, which is alleged to render the claims indefinite. Accordingly, the phrase "that may include cancer cells" has been deleted from claims 2 and 26. In addition, claims 2 and 26 are amended to recite a "minimum *prescribed* absorbed dose" to provide proper antecedent basis for dependent claims.

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Claims 4 and 28 are rejected for containing language which appears to claim a positive connection to the body. As helpfully suggested by the examiner, Applicant amends claims 4 and 28 to recite that the expandable surface element is "adapted to contact tissue surrounding a resected cavity and adapted to conform the tissue to the desired shape of the expandable surface element."

The Examiner rejects claims 5 and 29 for failing to include structure to support how the apparatus "creates absorbed isodose profiles." Applicant respectfully traverses the Examiner's indefiniteness rejections, for the following reasons. Amended claims 1 and 21 now recite that the radiation source disposed in the inner spatial volume generates a three-dimensional isodose profile. Inasmuch as claims 5 and 29 depend upon claims 1 and 21, respectively, the limitation that the radiation source generates the isodose profile should provide the sufficient structural support sought by the Examiner. Thus, Applicant respectfully argues that the structural support required for the limitations in claims 5 and 29 are present. Examiner is asked to kindly reconsider his rejections in view of amended claims 1 and 21.

Claim 14 was rejected for failing to provide antecedent basis for the limitation "the burst strength". In response, claim 14 is amended to provide antecedent basis for such limitation.

The Examiner rejects claims 22-29 for failing to recite method limitations in the active state. Accordingly, claims 22, 23, and 26-28 are amended to place such method steps in the active tense. Claims 24 and 25 further define structural limitations and therefore do not need to be placed in the active tense. However, claims 24 and 25 are amended to clarify that a structural limitation is being recited, not a method limitation. And claim 29, as written, is already in the active tense.

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Applicant believes that such amendments to claims 2, 4, 5, 14, and 22-29 satisfy the requirements of the examiner, and respectfully request that the indefiniteness rejections over those claims be withdrawn.

Response to the Non-Statutory Double Patenting Rejection

Claims 1-14 and 18-34 stand rejected under the judicially created doctrine of double patenting over claims 1-13 of U.S. Patent No. 5,913,813. Accordingly, provided herewith is a timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321(c) to overcome the Examiner's rejection based on a non-statutory double patenting ground, since the patent is commonly owned with this application. Applicant respectfully requests that the Examiner indicate receipt and acceptance of the terminal disclaimer, and withdrawal of the non-statutory double patenting rejection over claims 1-14 and 18-34 of the present application in his next correspondence.

Response to the Anticipation Rejection

Claim 1 stands rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Ishiwara et al., U.S. Patent No. 5,106,360 (hereinafter "Ishiwara"). Claim 1 also stands rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Weinberger, U.S. Patent No. 5,924,973. Based on the amendments and the following remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections under both Ishiwara and Weinberger.

Applicant's invention relates to an interstitial brachytherapy apparatus for providing radiation treatment to proliferative tissue in a living patient. The apparatus includes a catheter body member, an inner spatial volume disposed at a proximal end of the catheter body member, an outer spatial volume defined by an expandable surface element which surrounds the inner spatial volume, and a radiation source disposed in the inner spatial volume. The radiation source

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generates a three-dimensional isodose profile that is substantially similar in shape to the expandable surface element.

Turning to the cited prior art, the Ishiwara device comprises a thermotherapeutic apparatus having a catheter body member, an inner lumen surrounded by an outer lumen, and a radiation source contained within the inner lumen. As disclosed in col. 4, lines 19-23, Ishiwara's apparatus is inserted into a body cavity. See, e.g., Figure 4. Hence, the apparatus does not provide *interstitial* radiation treatment, as Applicant's invention requires, but rather intercavitary radiation treatment. Such a distinction is significant when considering the isodose profiles generated by the two devices. In the apparatus of Ishiwara, the isodose profiles do not take the shape of the outer lumen. Rather, the radiation source generates absorbed isodoses along the sides of the outer lumen, and not at the ends. This is because Ishiwara is concerned with tumor growth along a cavity, and therefore would not require radiation at the ends of the lumen.

Applicant respectfully reminds the Examiner that in a related parent application, 08/900,021, wherein Ishiwara was also cited, Applicant had argued that:

In the Ishiwara et al. '360 patent relied upon for anticipation, the outer chamber defined by the radiation transparent wall 12 cannot provide a uniform radiation profile. The outer balloon 12 in the Ishiwara et al. patent functions only to stabilize the device within and hold a thermal mass (liquid) against surrounding tissue so that it can be warmed or cooled by thermal conduction. There is no teaching or suggestion in the patent of how to provide a uniform radial absorbed dose profile of emissions emanating from the liquid radiation source 38. Moreover, given the banana shape of the Ishiwara device, the profile will be much different proximate the distal and proximal ends of the balloon 12 than in its central tissue contacting region. Thus, it cannot be said that applicants' invention, as claimed, is taught by or inherent in the Ishiwara '360 device.

In that instance, Applicant's arguments with respect to Ishiwara were deemed persuasive by the Examiner in the parent application. Applicant believes that much of the arguments

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proposed to the Examiner in the parent application are applicable to the present invention. Examiner is asked to kindly refer to Figure 5 of Ishiwara, which shows the banana shape of the device. As illustrated, the outer surface element is not substantially the same shape as the inner spatial volume. Therefore, the radiation source disposed in the inner spatial volume of Ishiwara would not generate a three-dimensional isodose profile that is substantially similar in shape to the expandable surface element.

Similarly, Weinberger discloses in Figure 17 an intercavitary radiotherapy device for insertion within a patient's lumen. See col. 4, lines 61-65 and col. 4, lines 22-28. Like Ishiwara, Weinberger's apparatus does not provide *interstitial* radiation treatment, as Applicant's invention requires, but instead *intraluminal* radiation treatment. Whereas Applicant's device treats disease that is embedded in tissue (e.g., breast cancer), Ishiwara and Weinberger treat disease in a luminal cavity. For this reason, in Ishiwara and Weinberger, the catheters and expandable balloons are very different than those of Applicant's invention. Ishiwara and Weinberger require a catheter that can work with a guidewire for insertion into a lumen, while Applicant's catheter does not need to work with a guidewire, since Applicant's apparatus is inserted into tissue rather than a hollow lumen. Effectively, this results in Applicant's catheter being differently sized and shaped relative to the catheters of Ishiwara and Weinberger. Applicant's catheter allows the inner volume to closely match the shape of the outer expandable element, hence allowing the radiation source inside the inner volume to generate a three-dimensional isodose profile that is substantially similar in shape to the outer expandable element.

In contrast, due to the configuration of the catheters, the inner volumes of Ishiwara and Weinberger are not substantially similar in shape to their outer expandable elements. The distinction is significant when considering the three-dimensional isodose profiles generated by the two devices. Ishiwara and Weinberger do not provide an apparatus that can produce isodose

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profiles that are substantially similar in shape to the outer lumen. For example, referring to Figure 17 of Weinberger, a large diameter catheter 200 runs through the double balloons 202, 204 of the device. It is clear from this illustration that, given the large size of the Weinberger catheter and the fact that the ends of the balloons do not generate absorbed isodose profiles, the device does not generate a three-dimensional isodose profile that is substantially similar in shape to the outer expandable element.

As amended, independent claims 1 and 21 require an interstitial brachytherapy apparatus having a radiation source disposed in the inner spatial volume that generates a three-dimensional isodose profile that is substantially similar in shape to the expandable surface element. These recitations are neither taught nor suggested by Ishiwara or Weinberger. As discussed *supra*, both Ishiwara and Weinberger disclose an intercavitary radiation device that operates differently and generates a different radiative effect than Applicant's interstitial radiotherapy device. Because Ishiwara and Weinberger fail to disclose each and every limitation of the claimed invention, the Examiner is kindly asked to reconsider his rejections under Ishiwara and Weinberger, and withdraw these rejections in his next office action.

Finally, since Ishiwara and Weinberger pertain to intraluminal radiation treatment devices rather than interstitial radiation treatment devices, Applicant urges that Ishiwara and Weinberger fail to disclose or teach an expandable surface element that is adapted to contact tissue surrounding a resected cavity and conform the tissue to the desired shape of the expandable surface element, as is recited in claim 4. In addition, because Ishiwara and Weinberger do not provide an apparatus that can produce isodose profiles that are substantially similar in shape to the expandable surface element, particularly in three dimensions, Applicant urges that claims 5 and 6 are not rendered to be anticipated or obvious by Ishiwara and Weinberger. Therefore, the

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Examiner is kindly asked to acknowledge the allowability of these claims in his next office action.

Claim 1 stands rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Bradshaw et al., U.S. Patent No. 5,662,580 (hereinafter "Bradshaw"). Based on the amendments and the following remarks, applicant respectfully requests reconsideration and withdrawal of the rejection under Bradshaw.

As discussed *supra*, Applicant's invention relates to an interstitial brachytherapy apparatus for providing radiation treatment to proliferative tissue in a living patient. The apparatus includes a catheter body member, an inner spatial volume disposed at a proximate end of the catheter body member, an outer spatial volume defined by an expandable surface element which surrounds the inner spatial volume, and a radiation source disposed in the inner spatial volume and generating a three-dimensional isodose profile that is substantially similar in shape to the expandable surface element.

In contrast to Applicant's invention, Bradshaw discloses an intercavitary radiotherapy device for insertion within a patient's blood vessel, rather than an interstitial radiotherapy apparatus. See col. 5, lines 11-14. Bradshaw's device thus does not create absorbed isodose profiles shaped substantially similar to the outer lumen of the device. The Examiner is kindly referred to the discussion *supra* for reasons why an intercavitary radiotherapy device functions in a different manner than an interstitial radiotherapy device, and hence produces a different isodose profile. Furthermore, Bradshaw discloses in col. 5, lines 15-30 that the *outer* lumen of the balloon catheter is filled with isotopes, rather than the inner lumen, as required in claim 1. Bradshaw therefore teaches the exact opposite of Applicant's claimed invention. Rather than have the isotopes radiate out from an internal lumen, the isotopes in Bradshaw are placed within

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the outer lumen contacting the vessel wall. For this reason, Applicant respectfully argues that the claimed invention is neither anticipated by or rendered obvious by Bradshaw. The Examiner is kindly asked to reconsider his rejection under Bradshaw and withdraw this rejection in his next office action.

Finally, since Bradshaw relates to an intraluminal radiation treatment device rather than an interstitial radiation treatment device, Applicant urges that Bradshaw fails to disclose or teach an expandable surface element that is adapted to contact tissue surrounding a resected cavity and conform the tissue to the desired shape of the expandable surface element, as is recited in claim 4. In addition, because Bradshaw does not provide an apparatus that can produce isodose profiles that are substantially similar in shape to the expandable surface element, especially in three dimensions, Applicant urges that claims 5 and 6 are not rendered to be anticipated or obvious by Bradshaw. Therefore, the Examiner is kindly asked to acknowledge the allowability of these claims in his next office action.

Claims 1 and 21-24 stand rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Williams, U.S. Patent No. 5,429,582. Based on the amendments and the following remarks, applicant respectfully requests reconsideration and withdrawal of the rejection under Williams.

Amended claims 1 and 21 now require that the interstitial brachytherapy apparatus comprise a radiation source disposed in the inner spatial volume and generating a three-dimensional isodose profile that is substantially similar in shape to the expandable surface element. As seen in Figure 7 of Williams, outer lumen 28B is not evenly spaced apart from inner lumen 28A that contains the radiation source. In this system, where the radiation source is provided as a liquid within the inner balloon, the shape of the three-dimensional isodose profile will correspond to the shape of the inner balloon. For this reason, Williams does not provide an

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apparatus that can generate a three-dimensional isodose profile that is substantially similar in shape to the expandable surface element, as is recited in the claims. That is, because the balloons are not equally spaced apart, Williams' apparatus cannot create an isodose profile that has substantially the same shape as the outer element. Hence, Williams fails to disclose each and every limitation of the claimed invention. Based on Applicant's arguments, the Examiner is kindly asked to reconsider his rejection under Williams and withdraw this rejection in his next office action.

Finally, since compression of the brain tissue surrounding the outer balloon 28B (see Figure 7) might prove detrimental to the health of the patient, Applicant urges that Williams fails to disclose or teach an expandable surface element that is adapted to contact tissue surrounding a resected cavity and conform the tissue to the desired shape of the expandable surface element, as is recited in claims 4 and 28. In addition, because William does not provide an apparatus that can produce isodose profiles that are substantially similar in shape to the expandable surface element, particularly in three dimensions, Applicant urges that claims 5, 6, 29, and 30 are not rendered to be anticipated or obvious by Williams. Therefore, the Examiner is kindly asked to acknowledge the allowability of these claims in his next office action.

Response to the Obviousness Rejections

Claim 25 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Williams.

On page 4 of the Office Action, the examiner asserts that:

Although Williams does not specifically disclose using the device to treat the breast, a modification of Williams to do so would have been obvious to one of ordinary skill in the art at the time the invention was made in that one skilled in the art would readily know that the device could be used in any part of the body to treat tissue surrounding a cavity left by surgical removal of a tumor.

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Applicant respectfully disagrees with the examiner's assertions and kindly refers the examiner to the discussion *supra* for reasons why Williams fails to satisfy the limitations of claim 21, as amended. Inasmuch as claim 25 depends upon claim 21, which claim was previously argued by applicant to be unanticipated by Williams, discussion of the rejection of claim 25 over the same prior art is rendered unnecessary. The Examiner is asked to kindly reconsider his rejection of claim 25 over Williams, and withdraw this rejection in his next office action.

Additionally, claims 15-18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Weinberger or Bradshaw in view of Clerc et al., U.S. Patent No. 6,059,812 (hereinafter "Clerc"). On pages 4 and 5 of the Office Action, the examiner asserts that:

Bradshaw et al and Weinberger disclose the claimed device except for the use of an expandable cage instead of a balloon. Clerc et al. discloses a self-expanding "cage" (12) that is used to help deliver radioactive therapy. Clerc et al. discloses the support having a shape memory such that it is self opening. Further to use any known shape memory material such as nitinol would have been obvious since nitinol is well known and conventionally used with radioactive therapy devices. Therefore a modification of Bradshaw et al or Weinberger such that a "cage" or support is used instead of a balloon would have been obvious.

For several reasons, applicant respectfully disagrees with the examiner's assertion that these combinations would satisfy the limitations of the claimed invention. In particular, Applicant respectfully disagrees with the examiner's assertions that Bradshaw and Weinberger disclose the claimed device except for the use of an expandable cage instead of a balloon. The Examiner is kindly referred to the discussion *supra* for reasons why both Weinberger and Bradshaw fail to clearly anticipate the claimed invention. Thus, inasmuch as claims 15-18 depend upon claim 1, which claim was previously argued by applicant to be unanticipated by Weinberger and Bradshaw, discussion of the rejection of claims 15-18 over the same prior art is rendered unnecessary.

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Because the admitted deficiencies of Weinberger and Bradshaw are not overcome by their combination with Clerc, applicant respectfully requests that the examiner withdraw the obviousness rejections under Weinberger and Bradshaw in view of Clerc in his next office action.

Finally, in reviewing the prior art cited by the examiner, Applicant urges that none of the references either anticipate or render obvious the

Newly Added Claims are Not Anticipated by the Prior Art

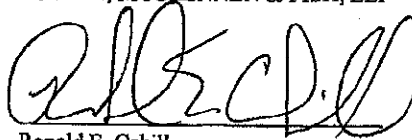
Newly added claim 35 depends upon claim 26, which claim was not rejected over prior art, and should therefore be allowable. New claim 36 includes all the limitations of claim 21 and claim 26, which claim was not rejected under prior art. Similarly, newly added claim 38 includes all the limitations of claims 21 and claim 28, which claim was not rejected under prior art. New claim 40 includes all the limitations of claims 1 and 2, which claim was not rejected over prior art. New claims 37 and 39 depend from new claims 36 and 38, respectively. Therefore, Applicant believes that new claims 35-40 are allowable over the cited prior art.

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For all of the foregoing reasons, Applicants request that the Examiner reconsider the rejection of claims 1-34 and allow claims 1-34, along with newly added claims 35-40 to issue. If the Examiner believes that an interview would facilitate the resolution of any outstanding issues, the Examiner is kindly requested to contact the undersigned.

Respectfully submitted,

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